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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,998	DAVIS ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☒ Claim(s) *10,11 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The restriction requirement filed March 17, 2008, is hereby withdrawn.

The preliminary amendment filed November 22, 2005, has been received and entered.

Claims 1-27 are pending and are examined on the merits.

Claim Objections

Claims 10, 11, and 24 are objected to because of the following informalities: The recitation "poly-2-acrylamido-2-methylpropane sulphonic acid" in claim 10 should be replaced with "poly(-2-acrylamido-2-methylpropane sulphonic acid)." The recitation "thehydrophilic" in the first line of claim 11 should be substituted with "the hydrophilic." The recitation "poly(-2-acrylamido-2-methylpropane sulphonic) acid" at the third line of claim 24 should be replaced with poly(-2-acrylamido-2-methylpropane sulphonic acid)." Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time te application was filed, had possession of the claimed invention.

Specifically, claim 15 recites that the hydrated hydrogel comprises 20% by weight of "a salt or salts" though the specification only refers to salt or salts thereof of poly(-2-acrylamido-2-

methylpropane sulphonic acid). No other salts are referred to in the specification. Thus, claims 15-17 are rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it is unclear how the skin dressing can comprise a first dressing component carrying oxidoreductase enzyme in dried condition when the claim requires that the enzyme is hydrated when the first and second dressing components are placed in fluid communication. It is not clear that claim 1 requires that the first and second dressing components are ever in fluid communication with one another. Thus, claims 1-27 are rejected under 35 U.S.C. 112, second paragraph.

Claims 1, 6, 7, 13, 15, 18, 19, 20, 21, 24, 25, and 27 are rendered obvious by the recitation of "first component," "second component," or "second components." Parent claim 1 first recites "first dressing component" and "second dressing component," thus for antecedent basis, the above should be replaced with "first dressing component," "second dressing component," or "second dressing components." See lines 4-6 of claim 1, line 2 of claims 6 and 7, line 1 of claims 13 and 15, line 2 of claims 18 and 19, lines 1 and 3 of claim 20, lines 2 and 3 of claim 21, lines 2 and 5 of claim 24, line 2 of claims 25 and 27. Thus, claims 1-27 are rejected under 35 U.S.C. 112, second paragraph.

Claim 7 is rendered indefinite by the recitation "carrier carrying enzyme." It is unclear whether the recitation is referring to a carrier that carries the oxidoreductase enzyme recited in claim 1. Thus, claims 7-11 are rejected under 35 U.S.C. 112, second paragraph.

Claim 11 is rendered indefinite by the recitation "preferably at least 2%, more preferably at least 5%, possibly at least 10%." The recitation of narrower ranges in the claim and the use of the term "preferably" makes the metes and bounds of the claim confusing. Also, the use of the term "possibly" leads to confusion over the intended scope of the claim. See MPEP 2173.05(c), Section I, and MPEP 2173.05(d).

Claim 23 is indefinite because of the recitation "especially sucrose and trehalose, glycerol and sorbitol." The metes and bounds of the claim are unclear as the listing of preferences leads to confusion over the intended scope of the claim. See MPEP 2173.05(d).

Claim 27 is rendered indefinite by the recitation "the first and second components are separately sealed in respective packages prior to use." This recitation implies a step, though claim 27 is drawn to a composition, not to a method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 12, 22, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Powell (US 4,327,731).

Powell discloses a system for indicating the presence of moisture in items including surgical dressings incorporating the moisture indicating system (column 1, lines 5-9). Figures 1 and 2 demonstrate embodiments of the invention and claim 3 describes an absorbent surgical dressing. Figure 1 shows an absorbent carrying medium 11 which supports a substrate 14 such a glucose and an enzyme catalyst 12 (column 4, lines 10-23). When the substrate is glucose, the oxidoreductase glucose oxidase may be the enzyme in the system (claim 7). Each of these elements are impregnated into different layers of absorbent paper (column 4, lines 24-29). Powell indicates that "when moisture is present and reaches the substrate material, it releases some of the substrate material into the adjacent enzyme and chromogen system, and visible color is produced" (column 3, lines 10-13). Clearly, when moisture seeps into only the absorbent carrying medium 11 and the substrate 14 layers, or only the absorbent carrying medium 11of the moisture indicating system, layers 11 and 14 or layer 11 alone is considered a "second dressing component carrying a source of water" while the enzyme catalyst 12 is considered a "first dressing component carrying oxioreductase enzyme in dried condition." Moreover, as the layers are absorbent and since the glucose in such a system becomes dissolved for reaction with the enzyme (column 3, lines 10-18), water indeed can migrate from the second component towards the first component and act to hydrate enzyme carried by the first component. Clearly instant claim 1 is anticipated, as are claims 2-4, 6, 7, and 12.

Note further that the underside of the absorbent carrying medium 11 may include an adhesive (column 5, lines 25-31), thus meeting the limitation recited in instant claim 26. Moreover, given that the absorbent layers are present in the Powell composition that may be successively more absorbent toward the outside and draw moisture away from the wearer, the

absorbent layers are of material that can be considered "hydration enhancers," thus meeting the limitation recited in instant claim 22.

A holding of anticipation is clearly required.

Claims 1-9, 11, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (WO 01/28600, listed in 11/22/05 IDS).

Green discloses a multilayered wound dressing which generally comprises a first sheet having an iodide, an oxidant or oxidant impregnated therein, and a second sheet having a proton donor (page 6, lines 20-22) wherein at least one of the first and second sheets comprises a lyophilized hydrogel (page 6, lines 24-25). See also Figures 2A and 2B. The "proton donating" layer of the bilayer sandwich is placed over the wound site with the proton source entering the wound fluid first (page 13, lines 27-31). The wound dressing is activated when the two layers are brought together and wetted (by body fluid or water introduced) (page 14, lines 6-9). The proton source can be oxidoreductase (page 9, lines 4-5) which may be glucose oxidase (page 21, lines 24-25). Furthermore, the bilayer design allows that when the two layers are brought together and wetted (either by body fluid or water introduced), the fluid permeating the layers brings the reactants together from which anti-infective iodine can be formed according to "equation 1" (page 14, lines 6-9). "Equation 1" shows that when hydrogen ions, iodide ions, and an oxidant are reacted together, iodine and water is produced (page 8, line 21). Thus, the first sheet comprising the iodide ions is considered a "second dressing component carrying a source of water" while the second sheet comprising the proton source is considered a "first dressing component carrying oxidoreductase in dried condition." In conclusion, instant claim 1 is

anticipated by the reference, as are instant claims 2, 3, and 5-9. Note that when the two layers are wetted, the water produced by the reaction in the "second dressing component carrying a source of water" according to the "equation 1" would indeed migrate to an extent towards the "first dressing component."

It is noted that the upper and lower layers of the bilayer dressing may be fabricated of the same polymer base (page 25, lines 1-14). Thus, instant claims 18, 19, and 21 are anticipated. Also, suitable hydrogels can include polyvinyl alcohols (page 17, lines 12-16). Moreover, instant claim 11 is anticipated (page 19, lines 19-21).

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell in view of Green, Munro et al. (US 2002/0037270) and Fuchs (US 5,483,697).

As discussed above, Powell anticipates claims 1-4, 6, 7, 12, 22, and 26. However, Powell does not disclose that its absorbent surgical dressing includes a supply of iodide ions. Furthermore, Powell does not expressly disclose that the material used as the absorbent carrying medium or to carry the enzyme catalyst and substrate is hydrogel material.

Green discloses a multilayered wound dressing that comprises iodide wherein the layers can comprise lyophilized hydrogel (page 6, lines 20-25). In combination with an oxidoreductase and a substrate, the Green wound dressing can generate anti-infective iodine from the iodide present (page 9, lines 2-7). It is noted that the upper and lower layers of the Green bilayer dressing may be fabricated of the same polymer base (page 25, lines 1-14). Moreover, the material used meets the concentration requirements recited in instant claim 11 (page 19, lines 19-21).

Munro et al. discloses wound dressings comprising hydrogel compositions having bioadhesive properties (page 1, paragraph [0001]). In the dressing, interpenetrating polymer networks (IPN) are used in the hydrogel and may include water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (page 4, paragraph [0054]). Munro et al. notes that "...polymerising and crosslinking water soluble monomers in the presence of water soluble polymers, water and polyhydric alcohols produces hydrogel materials with enhance rheological and consequently adhesive properties" (page 4, paragraph [0053]).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have substituted the absorbent paper used in the surgical dressing with hydrogels which encompass those described in Green for wound dressings or hydrogel compositions described in Munro et al. for wound dressings (comprising poly(2-acrylamido-2-methylpropane-sulphonic acid) or salts thereof). One of ordinary skill in the art would have been motivated to do this because it would have been obvious to substitute one known wound dressing material for another to achieve the predictable result of treating wounds. The skilled artisan would have been motivated to use water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts since they are known components of hydrogels for wound dressings and because it would have enhanced the rheological and adhesive properties of the dressing. It is noted that hydrogel material is shown by Green to be suitable for carrying oxidoreductases. Additionally, it would have been obvious to the person of ordinary skill in the art to have included iodide in the Powell dressing since, in combination with glucose oxidase and glucose reaction system, since it would have resulted in the production of anti-infective iodine when applied to wound. Thus, instant claims 5, 8-11, 13, 14, and 18-21 are rendered obvious.

Furthermore, the selection of specific concentration of poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts and water in the hydrated hydrogel would have been a matter of routine optimization and experimentation on the part of the skilled artisan. Thus, instant claims 15-17 and 24 are rendered obvious.

The references also differ from the claimed invention in that they do not expressly disclose the presence in the wound dressing of a hydration enhancer or a moisturizer material.

Fuchs discloses that "The addition of humectants such as sorbitol, glycerol, sugar, corn syrup and other polyhydroxy compounds may help to retain moisture in the hydrogels" (column 9, lines 30-32).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have included the humectants such as those listed in Fuchs in the hydrogel wound dressing rendered obvious by Powell, Green, and Munro et al. One of ordinary skill in the art would have been motivated to do this since it would have permitted retention of moisture, thus assisting in the reaction of the oxidoreductase with the substrate. Note that sorbitol and glycerol are among the compounds listed in instant claim 23 as "hydration enhancers," and amongst the compounds listed in the first paragraph on page 15 of the disclosure as "moisturiser materials." Thus, claims 23 and 25 are rendered obvious.

Finally, the references differ from the claimed invention in that they do not expressly disclose that the first and second components are separately sealed in respective packages prior to use. However, it would have been obvious to have kept the components separate in order to minimize bacterial contamination and prevent the reaction from taking place prior to treating a wound. Thus, claim 27 is rendered obvious.

A holding of obviousness is clearly required.

Claims 1-11 and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Munro et al. and Fuchs.

As discussed above, Green anticipates claims 1-9, 11, 18, 19, and 21. However, Green does not expressly disclose that the hydrogel material comprises poly(2-acrylamido-2-methylpropane-sulphonic acid) or salts thereof.

Munro et al. discloses wound dressings comprising hydrogel compositions having bioadhesive properties (page 1, paragraph [0001]). In the dressing, interpenetrating polymer networks (IPN) are used in the hydrogel and may include water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or one of its salts and its copolymers (page 4, paragraph [0054]). Munro et al. notes that "...polymerising and crosslinking water soluble monomers in the presence of water soluble polymers, water and polyhydric alcohols produces hydrogel materials with enhance rheological and consequently adhesive properties" (page 4, paragraph [0053]).

One would have been motivated to use water soluble polymers such as poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts since they are known components of hydrogels for wound dressings and because it would have enhanced the rheological and adhesive properties of the dressing. Furthermore, the selection of a specific concentration of poly(2-acrylamido-2-methylpropane-sulphonic acid) or its salts would have been a matter of routine optimization and experimentation on the part of the skilled artisan. Thus, instant claims 10, 20, and 24 are rendered obvious.

Green also differs from the claimed invention in that it does not teach that the first dressing component comprises hydration enhancers, or that the first and/or second dressing components include moisturizer materials.

Fuchs discloses that "The addition of humectants such as sorbitol, glycerol, sugar, corn syrup and other polyhydroxy compounds may help to retain moisture in the hydrogels" (column 9, lines 30-32).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have included the humectants such as those listed in Fuchs in the hydrogel wound dressing of Green. One of ordinary skill in the art would have been motivated to do this since it would have permitted retention of moisture, thus assisting in the reaction of the oxidoreductase with the oxidase. Note that sorbitol and glycerol are among the compounds listed in instant claim 23 as "hydration enhancers," and amongst the compounds listed in the first paragraph on page 15 of the disclosure as "moisturiser materials." Thus, claims 22, 23 and 25 are rendered obvious.

Green does not expressly disclose that the wound dressing includes a covering/outer layer for adhering the dressing to the skin. Nevertheless, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Green invention to include an adhesive layer on the dressing. Moreover, the adhesive layer could be one of the types of layers discussed in Green (page 25, first paragraph). Given that the Green invention can include poly(2-acrylamido-2-methylpropane-sulphonic acid), the hydrogel itself can be considered an outer layer for adhering the dressing to the skin. One of ordinary skill in the art would have been motivated to include an adhesive layer since an adhesive layer would have ensured that the Green wound dressing is maintained at the wound site. Thus, claim 26 is rendered obvious.

Finally, Green differs from the claimed invention in that it does not expressly disclose that the first and second components are separately sealed in respective packages prior to use. However, it would have been obvious to have kept the components separate in order to minimize bacterial contamination and prevent the reaction from taking place prior to treating a wound. Thus, claim 27 is rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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